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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,217

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Randolf Von Oepen

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12/17/2009

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,217	Applicant(s) VON OEPEN ET AL.	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38-49 and 73-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38-49 and 73-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/1/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 76-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 76 includes a bar having a first bore extending laterally therethrough and a second bore extending longitudinally from the proximal end to the distal end and a filament slidably disposed through both. However, only bores extending laterally through the bore are disclosed in the application and there is no written description of a bar with both a first bore extending laterally therethrough and a second longitudinally extending bore that extends from the proximal end to the distal end of the bar.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 36, 38-40, 44, and 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (Re 36,974) in view of Kim (US 5,810,884). Bonutti '974 discloses an apparatus for facilitating sealing of a puncture formed in a proximal later surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first bore extending laterally therethrough and a filament having first and second free ends, the filament being slidably disposed through and slidably removable from the first bore (see fig. 20), the bar being slidable relative to the filament. Bonutti '974 discloses a delivery sheath in which the filament and bar are disposed but fails to disclose a sharpened tip at the distal end.

6. However, Kim teaches that it is well known in the art to include a sharpened tip (48) on the distal end of a delivery device used to deliver a suture retaining element. The sharpened tip is tapered which facilitates its insertion into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. It would have been well within the purview of one skilled in the art to use such a sharpened tip on the delivery sheath of Bonutti '974 as taught by Kim because one skilled in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

7. Regarding claim 38, the device further comprises a push rod (82) disposed in the lumen proximal of the bar.

8. Regarding claim 39, the bar is cylindrical.

9. Regarding claim 40, the bar may be biodegradable (see col. 3, ll. 40-41).

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10. Regarding claims 44 and 48, Bonutti '974 discloses two bores (fig. 20). The bore (186) is being considered disposed in a central region of the bar.

11. **Claims 41-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti '974 in view of Kim as applied to claim 36 above and further in view of Nash et al. (US 5,411,520). Bonutti '974 in view of Kim discloses the invention substantially as stated above but fails to disclose a tensioning device configured to hold the filament in a tensioned state.

12. However, Nash et al. discloses that it is old and well known in the art to include a tensioning device in devices used to facilitate the sealing of a puncture. Nash et al. discloses that such a tensioning device is necessary in order to maintain appropriate tension of the filament while the delivery sheath is removed (col. 14, ll. 29-35). The tensioning device is shown in figs. 13, 14, and 26. It comprises an upright (142) having upper and lower ends, a plurality of legs attached to the lower end, and a grip affixed to the upper end. The legs are being considered the two pieces defined by the slit (142D) at the lower end of (142) and the grip is the portion attached to the upper end of (142) that also has a slit (142D). Regarding claim 43, the grip comprises a V-shaped groove formed in the tensioning device formed in the flexible material of the tensioning device, which is being considered an equivalent alternative to an elastomeric material. Although the material can be plastically deformed, it would have been obvious to one skilled in the art to use an elastomeric material since one skilled in the art would have recognized the advantage of having a groove that, in its closed state with no filament therein, is thinner than the diameter of the filament in order to have a stronger grip on the filament. In order to place the filament in such a groove, a material such as an elastomeric material that can be deformed but returns back to its original configuration would have been an obvious material choice to one skilled in the art. It would have been within the purview of one skilled in the art to be able to form grips similar to the louvers with an elastomeric material.

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Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Bonutti '974 to include a tensioning device as made obvious by Nash et al. in order to gain the advantage of maintaining appropriate tension of the filament while removing the delivery sheath.

13. **Claims 45-47 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti '974 in view of Kim as applied to claim 36 above and further in view of Rollero et al. (US 6,506,197). Bonutti '974 in view of Kim discloses the invention substantially as stated above including the use of either a bore or an eyelet through which a filament is threaded since Kim teaches threading a filament (14) through an eyelet (104). Kim further teaches using an eyelet and bore on the same bar (fig. 9a) so that a filament (14) may be threaded through both for additional control over the bar. Bonutti '974 in view of Kim fails to disclose the filament slidably disposed through the first bore, then the eyelet, then back through the first bore.

14. Rollero et al. discloses that it is old and well known in the art to include a plurality of attachment points, such as holes, in a bar such that a filament can be securely attached to the bar (see fig. 6a and 6b). This configuration includes a bore in the central region and in the distal region when the bar is inserted using the delivery sheath of Bonutti '974. The filament is disposed through a central bore, then a bore in a distal region of the bar, then back to the central bore in order to provide a more secure attachment of the bar to the filament (see figs. 6a-6c). It would have been obvious to one of ordinary skill in the art to employ a plurality of attachment points through which the filament is slidably disposed as made obvious by Rollero et al. in the device of Bonutti '974 so that suture can be attached to the bar more securely if desired.

15. Regarding claim 49, Rollero et al. makes obvious a plurality of bores wherein one of the bores is in a central region and one bore is disposed in a distal region of the bar.

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16. **Claims 73-78** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti '974 in view of Bonutti (US 5,814,073; "Bonutti '073"). Bonutti '974 discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar (fig. 20) having proximal and distal ends and a first bore extending laterally therethrough, the bar having a distal end having a generally planar surface oriented parallel to the bore, a filament (182) having first and second free ends, the filament being slidably disposed through and slidably removable from the first bore, the bar being slidable relative to the filament, and a delivery sheath (80) having proximal and distal ends, and a lumen extending therebetween to contain the bar and filament. Bonutti '974 fails to expressly disclose that the delivery sheath has a sharpened tip at the distal end that is disposed upon a peripheral longitudinal side of the delivery sheath.

17. However, Bonutti '073 teaches that it is well known to use an inserter with a sharpened tip at its distal end that is disposed upon a peripheral longitudinal side of the delivery sheath (figs. 5-9). The sharpened tip facilitates insertion of the anchor into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. It would have been well within the purview of one skilled in the art to use such a sharpened tip delivery sheath as taught by Bonutti '073 to deliver the bar of Bonutti '974 so that it too may have these advantages.

18. Regarding claim 74, the bar of Bonutti '974 is cylindrical (fig. 20).

19. Regarding claim 75, the bar of Bonutti '974 is cylindrical. However, applicant has not disclosed any criticality to the shape of the bar or any advantages associated with a rectangular bar as opposed to a cylindrical bar. Applicant states that "it will be apparent to those skilled in the art that while bars 22 and member 32 of figs. 1a-1d are illustratively shown having cylindrical and oval-shaped configurations, respectively, other configurations advantageously may be

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provided to perform the functions described hereinbelow". Therefore, it appears to the examiner that, when the prior art teaches a cylindrical bar, it will be apparent to those skilled in the art that other shapes can be used. Furthermore, it has been held that a mere change in shape of an element absent persuasive evidence that the particular configuration of the claimed element is significant involves only routine skill in the art (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)).

20. Regarding claim 76, the bar of Bonutti '974 is cylindrical and includes a lateral bore (186 to 184 for example) and a longitudinal bore (the bar is hollow and has a lumen that stretches between the proximal and distal ends) stretching from one end to the other. The filament can be considered slidably disposed through and removable from both bores since the filament is within both bores and can be slidably removed therefrom.

21. Regarding claim 77, Bonutti '974 discloses that the bar may be biodegradable (col. 3 ll. 40-42).

22. Regarding claim 78, Bonutti '073 teaches a sheath with a handle disposed at its proximal end (for example, ring 186 of sheath can be grasped).

Response to Arguments

23. Applicant's arguments filed 10/1/2009 regarding the combination of Bonutti ('974) in view of Kim (US 5,810,884) have been fully considered but they are not persuasive. Regarding the combination of Bonutti in view of Kim, Applicant argues that it would not have been obvious to one skilled in the art to add the sharpened tip taught by Kim to the delivery device of Bonutti because Bonutti discloses that it is preferable to insert the anchor directly through the soft tissue, not into an opening formed in the tissue. However, this is not found persuasive. Bonutti discloses that the anchor may have a slightly sharpened tip to push through tissue layers. Adding a sharpened tip to the delivery device will work in a similar manner to a sharpened

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anchor and is advantageous because the sharpened surface is removed so as not to aggravate surrounding tissue. Bonutti discloses forming a hole in bone using a drill and then using a separate delivery device to deliver the anchor and it appears to the examiner that Bonutti is merely pointing out that a preformed hole is not needed in the case of soft tissue since the sharpened anchor, or similarly a sharpened delivery device, can be used to separate the tissue enough to insert the anchor without pre-forming a hole.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,030,007 to Bassily et al. discloses an anchoring device with a filament disposed through a lateral and longitudinal bore; US 1,452,338 to Flowers discloses an anchoring device with a filament disposed through a lateral and longitudinal bore (fig. 1); US 5,366,480 to Corriveau et al. discloses a rectangular bar as an alternative to a cylindrical bar used to fasten suture to tissue (figs. 1-6a); US 5,219,359 to McQuilkin et al. discloses a rectangular bar used to fasten suture to tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 12/10/2009

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
12/15/09